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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,163	12/21/2001	Audra L. Stinchcomb	ACP-0001	6957

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,163	STINCHCOMB, AUDRA L.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8-10, 29, 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6, 8-10, 29, 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date __.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment and request for extension of time, both filed 02/14/2005.

Claims 2-6, 8-10, 29, and 30 are included in the prosecution.

Claim Rejections - 35 USC § 112

1. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is confusing because it depends on claim 29 that has the closed language "consisting essentially of" that does not permit the addition of other ingredients to the composition, such as the opiate of claim 10. Clarification is requested.

Response to Arguments

2. Applicant's arguments filed 02/14/2005 have been fully considered but they are not persuasive. Applicant argues that the amended claim 10 makes clear that the opiate is delivered with the cannabinoid composition rather than as part of the cannabinoid composition.

In response to this applicant argument, the examiner position is that the claim recites that opiate is delivered with the cannabinoid. The claim reads as the opiate can

be part of the cannabinoid composition and not as a separate transdermal delivery by another device. Opiate is a determinant ingredient that may alter the method of claim 29 in term of doses and regimen of administering cannabinoid.

Claim Rejections - 35 USC § 102

3. Claims 6, 8, 9, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/53917 ('917).

WO '917 disclosed a method for using cannabidiol in subjects who have been exposed to cancer chemotherapy or who have HIV (page 10, lines 4-6, 34; page 11, lines 19-21; page 20, lines 32-34; page 33, claim 14). The cannabidiol can be administered transdermally or topically (page 23, lines 17-20). The symptoms of chemotherapy are inherent for a specific chemotherapeutic agent.

The limitations of claims 6, 8, 9, 29 and 30 are met by WO '917.

Response to Arguments

4. Applicant's arguments filed 02/14/2005 have been fully considered but they are not persuasive. Applicant traverses this rejection by arguing that the reference does not teach method for relieving symptoms associated with illness as recited in claim 29, rather the reference teaches method of using cannabinoids as antioxidants.

In response to this argument, the examiner position is that the reference disclosed the same conditions and symptoms claimed by applicant that can be treated by cannabinoid topically. The reference disclosed treating HIV and nausea and vomiting that are associated with cancer chemotherapy. The mechanism by which symptoms are

relieved is not particularly critical to the practice of the present invention, as per applicant disclosure at page 5, lines 22-24. In any event, applicant does not claim any mechanism for relieving symptoms.

5. Claims 2-6, 8-9, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,328,992 ('992).

US '992 disclosed transdermal structure for delivering cannabis for the treatment of nausea and pain associated with cancer chemotherapy and wasting associated with AIDS, that reads on claims 1 and 6 (abstract; col.1, lines 24-30). Cannabis means any one or more or mixture of compounds or chemical components including cannabidiol, that reads on claims 1 and 7 (col.2, lines 47-53; col.7, lines 54-58). The transdermal structure comprises patches, bandages or covering, that reads on claims 8 and 9 (col.1, lines 58-60). The patch is occlusive and comprises backing layer; rate controlling membrane; reservoir positioned between the backing and the rate controlling membrane and comprises the active agent in a suitable carrier; and an adhesive means, that reads on claims 2, 3, and 5 (col.2, lines 6-10, 21-24; col.3, lines4-8, 25-28, 49-51, 64-67; col.4, lines 66-67; col.5, line 1). The suitable carrier includes gel, that reads on claim 4 (col.3, lines 37-45).

The limitations of claims 1-6,8, 9, 29 and 30 are met by the US '992 reference.

Response to Arguments

6. Applicant's arguments filed 02/14/2005 have been fully considered but they are not persuasive. Applicant traverses this rejection by arguing that the reference discloses

administration of mixture of cannabinoids while the present claims require composition "consisting essentially of cannabidiol".

In response to the above argument, the examiner position is that the claims are anticipated by US '992 because the reference disclosed the transdermal administration of cannabinoid mixture including cannabidiol (CBD). The expression "consisting essentially of" limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte,* 337 F 2d 870, 143 USPQ 256 (CCPA 1964). The reference choice to combine CBD with other cannabinoids does not make the present claims patentable. The art recognized the transdermal administration of composition comprising CBD to relieve the symptoms associated with cancer chemotherapy and wasting associated with HIV infection. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain. *In re Heck*, 699 F.2d 1331, 1332—33, 216 USPQ 1038, 1039 (Fed. Cir 1983).

Claim Rejections - 35 USC § 103

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '917 or US '992 in view of PGPB 2003/0158191 ('191).

The teachings WO '917 and US '992 are discussed under 102 rejection above.

The references do not teach the inclusion of opiate with the transdermal delivery of cannabis derivatives.

PGPB '191 teaches a combination of cannabis derivatives delivered transdermally with other active agents including morphine page 2, 0012; page 10, 0214; page 14, 0356; page 15, 0359, 0362). The reference teaches that the combination therapy may allow for increased efficacy and potentially reduces side effects (page 16, 0370).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide cannabidiol delivered transdermally as taught by any of WO '917 or US '992 and add opiate in the transdermal system as taught by PGPB '191, motivated by the teaching of PGPB '191 that the combination therapy may allow for facilitating increased efficacy and potentially reduces side effects, with reasonable expectation of having a device that delivers cannabis derivatives and opiate with increased efficacy and reduced side effects.

8. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '917 in view of US '992.

The teachings of WO '917 and US '992 are discussed under 102 rejection above. However, WO '917 does not teach structure of the transdermal device used to deliver the cannabidiol.

The occlusive transdermal device disclosed by US '992 is advantageous as it allows controlled delivery of the cannabinoid over a predetermined period of time such that plasma level of cannabinoid may be controlled in a safe, convenient and effective manner for the patient (col1, lines 58-65).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal delivery of cannabidiol as disclosed by WO '917, and select the occlusive delivery device disclosed by US '992, motivated by the teachings of US '992 that the occlusive transdermal device is advantageous as it allows controlled delivery of the cannabinoid over a predetermined period of time such that plasma level of cannabinoid may be controlled in a safe, convenient and effective manner for the patient, with reasonable expectation of having an occlusive transdermal device that delivers cannabidiol in safe, convenient, effective and controlled manner to the patients in need of such treatment.

Response to Arguments

9. With regard to the rejection of the claim 10 under 35 U.S.C. 102(e) as being unpatentable over WO '917 or US '992 in view of US '191, and rejection of claims 2-5 under 35 U.S.C. 103(a) as being unpatentable over WO '917 in view of US '992, applicant has failed to traverse the rejection and the response is considered to be

acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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